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Dear Ms. Mohandessi-Fares,

The Yuba-Sutter Healthcare Council very much appreciates both the dedication which CalOHII brought to the task of reviewing and respecting the many public comments received on the initial draft regulations and the opportunity to again provide comment.

The revised regulations clearly show that CalOHII was diligent in its review of the public comments and sought to find a much better balance between privacy and access in order to support effective HIE in California and enable Californians to benefit from its potential to improve quality and reduce costs.

The Council has far fewer concerns about these revised regulations and offers several comments in support of specific revisions.

Support

Thank you for each of the following:

- amending §126010 (b) to clearly state that these regulations will sunset and are thus not intended to become permanent regulations for HIE outside of the documentation project.
- amending §126050 with (a)(4) to support all HIPAA permitted transactions, including: health care claims or equivalent encounter information, health care payment and remittance advice, coordination of benefits, health care claim status, enrollment and disenrollment in a health plan, eligibility for a health plan, health plan premium payments, referral certification and authorization, first report of injury, and, health claims attachments.
- permitting a centralized consent registry.
- improving the clarity of definitions.
- delineating the process for requesting alternative requirements.
- aligning State regulation much more closely with federal HIPAA regulation.
- eliminating many burdensome and overly prescriptive security methods.

Amendments

§126040 (c) [page 9] If CalOHII intends for the “employee or agent” to represent a Participant, it might be worth adding language to clarify, e.g. “employee or agent of a Participant”

§126060 (b)(3)(A)(iii) [page 15] in order to permit assessment of security and direct patients to any historical privacy breaches, after the word “provisions” please add something similar to: “and any reported HIPAA privacy breaches or unreported inadvertent data loss or releases”

§126076 (a) [page 23] should indicate that only secure methods of email are permissible for the sharing of PHI. Consider adding language after the word “shall” to the effect of: “not permit unencrypted or otherwise unsecured email of IHI and shall”.

Substitutions

Though stated in our prior remarks, it does not appear that this concern was addressed in any way. Perhaps due to the volume of comments received this issue was missed, but if left unchanged, it has the potential to create a catch 22 for providers. We modified our proposal to clarify that a requested change will be made, but how the change is reflected is up to the entity.

§126030 (a)(3)(C) [page 7]: Challenge the accuracy of their individual health information and, if successful, to have the individual health information corrected, completed, or amended.

proposed substitute language: Provide data or opinion which contradicts or mitigates the health information in their record and have this material incorporated in their record as a replacement, amendment or comment. The method of update shall be at the sole discretion of the entity.

Rationale: Not only does the current language leave out who determines whether the patient's challenge was successful, it also ignores the rights and responsibilities of the entity to be the caretaker of the record. Healthcare entities from individual provider practices to multifacility institutions are ultimately responsible for the accuracy of each patient's medical record and must therefore retain control over how this intended provision is implemented. While a patient may say "I do not have HIV", if the lab result says otherwise, the entity must be authorized to make the decision about whether to add the patient's statement as a comment or a fact.

§126040 (b)(2) [page 9] While the Council appreciates the concern expressed by CalOHII about terms within an EHR vendor agreement that may have impact on HIE, we would suggest that the majority of the EHR vendor agreement is not relevant. We would suggest amending this new section to specify which clauses, perhaps by their content, are relevant to CalOHII in its supervision of the demonstration projects.

§126060 (b)(2)(C) [page 14] There are serious risks for the misuse of PHI in allowing secondary data uses, even when deidentified. CalOHII should either prohibit use of deidentified data until clear policies are promulgated or consider language such as the following:

“If the Participant proposes to use or share deidentified data, the Participant shall explicitly share all algorithms and reasons which support Participant's contention that data cannot be reidentified. The names and contact information for all recipients of the data shall be provided to CalOHII to enable monitoring of data clustering from multiple HIOs or subsequent reidentification. Recipients must agree not to further disclose the deidentified data and shall report any changes in their contact information to CalOHII within 10 business days.”

§126060 (b)(3)(B)(vi) [page 15] should apply to all entities and thus should be expanded by replacing “the system vendor” with “any entity”. No one should repurpose or redirect patient data without the patient's explicit consent or under any of the previously stated exceptions.

Deletions

§126050(c) [page 11] is problematic and should be deleted. While the intent appears to be that HIPAA rules do not apply to fax and email exchange, within the context of this section it actually implies that secondary disclosure of data by fax or email is permitted. The Council believes that should not be the case. If it is important to indicate that these regulations in toto do not apply to fax transmissions, perhaps that statement should be made at the beginning of the regulations in a prologue while clearly stating that you are describing fax between two parties **not** involving HIE. At the present time, no PHI should be transmitted by unsecured email. Management of email data requires its own set of requirements and should not be mentioned here.

§126060 (b)(3)(B)(iv) [page 15] creates an unnecessary barrier above and beyond HIPAA. Sharing of most sensitive health data (e.g. pregnancy test, cancer finding) is permitted by law. §126060 (b)(3)(B)(v) addresses that the information is not about another individual and is redundant here. Please delete this clause.

Thank you again for your past efforts to harmonize the many public comments you received and develop these revised regulations. These regulations much better reflect the shared goal of CalOHII and the medical community, seeking to ensure the best care available to patients while promoting privacy and security of personal health information.

Respectfully,



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